Although anti-D Immunoglobulin (Ig) is technically not a blood component, but a prescription only medicinal blood product, the lessons we can learn from the process of requesting, testing, issue and administration are reflective of, and can be applied to transfusion as a whole. Physiological reactions to anti-D are not reportable to SHOT, but should instead be reported via the MHRA ‘Yellow Card’ scheme https://yellowcard.mhra.gov.uk/

Numbers of reports relating to process errors around anti-D Ig have risen steadily from just 5 cases in 1998 to 359 in the latest reporting year, 2014. This surely reflects a growing awareness of the benefits of reporting and learning from errors rather than a major deterioration in standards of practice.

### Anti-D Cumulative errors 1998 - 2014

<table>
<thead>
<tr>
<th>Type of event</th>
<th>No. Cases</th>
<th>Midwife / Nurse</th>
<th>Laboratory</th>
<th>Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omission or late administration of anti-D Ig</td>
<td>1363</td>
<td>1187</td>
<td>122</td>
<td>54</td>
</tr>
<tr>
<td>Anti-D Ig given to D positive woman</td>
<td>355</td>
<td>202</td>
<td>138</td>
<td>15</td>
</tr>
<tr>
<td>Anti-D Ig given to woman with immune anti-D</td>
<td>165</td>
<td>82</td>
<td>80</td>
<td>3</td>
</tr>
<tr>
<td>Anti-D Ig given to mother of D negative infant</td>
<td>96</td>
<td>15</td>
<td>81</td>
<td>0</td>
</tr>
<tr>
<td>Anti-D Ig given to wrong woman</td>
<td>70</td>
<td>66</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Wrong dose of anti-D Ig given</td>
<td>99</td>
<td>37</td>
<td>58</td>
<td>4</td>
</tr>
<tr>
<td>Anti-D Ig given when expired, out of temperature control or wrongly labelled</td>
<td>89</td>
<td>43</td>
<td>44</td>
<td>2</td>
</tr>
<tr>
<td>Totals</td>
<td>2237</td>
<td>1632</td>
<td>524</td>
<td>81</td>
</tr>
</tbody>
</table>

Midwives (and to a lesser extent nurses) are most often implicated in reports around anti-D Ig, being cited in 1632 (73%) of cases. This should not surprise, as midwives are integrally involved in the process. Laboratory staff consistently contribute to around 23.5% of reports, with medical staff, often at relatively senior level, involved in 3.5% of cases, both in hospital and in primary care.

### System Failures identified by SHOT

1. A lack of communication between hospital and community midwifery teams, and between both midwifery teams and the laboratory
2. Assumption that someone else is picking up the issue, or has done their job correctly, and a failure to take responsibility for the woman
3. Manual transcription of blood grouping results onto notes, care plans and discharge sheets in the clinical area persists despite being repeatedly highlighted by SHOT as poor practice
4. A demonstrable lack of knowledge and training, compounded by the holding of anti-D Ig stocks in the clinical area with little oversight by the laboratory
5. Decision-making, issuing and administration of anti-D Ig without reference to blood grouping results or electronic information management systems, in both the laboratory and clinical area
6. Putting the onus on the woman to return for anti-D Ig when she is variously frightened, traumatised, ill or has her hands full with a new baby, instead of issuing it at presentation
7. A lack of robust systems to identify women who need RAADP
8. A lack of robust systems to identify outstanding work in the hospital laboratory
9. A lack of robust systems for dealing with women who book late or transfer their care
10. An increasing trend of poor advice being given by medical staff, often at relatively senior level, particularly following potentially sensitising events.
11. Understaffing and availability of senior staff in both the laboratory and the clinical area leading to pressured and poor decision-making.
12. A culture of completing discharge paperwork when the interventions have not actually been performed.
13. Misinterpretation and misuse of the Kleihauer Test to determine issue of anti-D Ig
1. It does not really matter whether staff follow BCSH, NICE or RCOG guidance, or even a combination of all three as long as there is a robust, consistent Trust policy in place.
2. Current blood grouping and antibody screen results must be referred to when making decisions whether to issue or administer anti-D Ig.
3. If there is doubt about the D type, or whether detectable anti-D is immune or prophylactic, then anti-D Ig prophylaxis should be continued until the issue is resolved.
4. All healthcare professionals involved in the issue and administration of anti-D Ig must complete the anti-D modules in the Learn Blood Transfusion e-learning programme www.learnbloodtransfusion.org.uk
5. Anti-D Ig must be made readily available for administration to women when they present, rather than asking them to return for it at a later date.
6. Peak levels of prophylactic anti-D following administration of 1500 IU anti-D Ig will very rarely exceed 0.2 IU/mL if administered intramuscular (IM) or 0.4 IU/mL if administered intravenous (IV).
7. It is important that regardless of any prior administration of anti-D Ig, any anti-D detected at 28 weeks is quantified and the results made available in the maternity notes.
8. Anti-D Ig should be subject to the same standards of patient identification (ID) and traceability as blood components.
9. A larger dose of anti-D Ig should be given following delivery of a D positive child when cell salvage is used – BCSH recommend 1500 IU as a standard dose.
10. All organisations involved in the issue and administration of anti-D Ig must ensure that their systems are robust with respect to issue, receipt and recording, and should audit their systems to increase the safety and security of the process.
11. The BCSH Fetomental Haemorrhage (FMH) guidelines state that any FMH >2mL by Kleihauer should be confirmed by Flow Cytometry (FC), using the original sample. If the FC result will not be available within 72 hrs, the Kleihauer Test should be repeated (from scratch) by a second operator and the results acted upon.
12. Women who produce anti-D for the first time in the current pregnancy should be notified to SHOT for inclusion in the anti-D immunisation study.
13. Trusts should develop the idea of midwifery ‘champions’ who can lead on training, education and policy.

To improve understanding of the causes of continuing anti-D immunisations, SHOT is conducting a prospective study of women who have produced immune anti-D detected for the first time in the current (index) pregnancy. Reporters are requested to provide data on booking weight, management of sensitising events during pregnancy and the administration of routine anti-D prophylaxis, both in the index pregnancy and the pregnancy immediately before the index pregnancy (if applicable)

**SHOT Key Recommendation around Anti-D Ig**

There is no need for a ‘confusion’ of differing guidelines - hospitals and trusts should develop their own agreed protocol for administration of anti-D Ig, with multidisciplinary engagement from the laboratory, midwives, gynaecologists and obstetricians, which ensures that a consistent approach is adopted. These guidelines must also be adopted by other services with which women may come into contact following sensitising events, including primary care and emergency departments.

To assist in standardisation of the process, SHOT has developed a flowchart for the administration of anti-D Ig, now formally adopted by both BCSH and the RCOG, and the SHOT Office will produce a bespoke version for a particular hospital on request to: shot@nhsbt.nhs.uk